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09/802,668	03/09/2001	Steven L. Roberds	PHRM-0319	3061

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/802,668	Applicant(s) ROBERDS ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) *95 and 96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-94, 97-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 95-96 are withdrawn from consideration as being in uninterpretable and, accordingly, are not further treated on the merits.

2. Applicant is advised that the claims of Groups I-VII, IX-XII, XV, XIX-XXXVI are drawn to a multitude of nucleic acids and, respectively, to a multitude of polypeptides. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/ polypeptides is independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-VII, IX-XII, XV, XIX-XXXVI, Applicant is additionally required to elect a single nucleic acid or polypeptide. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29 and 64-68, 75, drawn to nucleic acid molecules encoding 52 (fifty-two) unrelated proteins, vectors, host cells and methods of protein production, classified in class 435, subclass 69.1, for example.

II. Claims 30-35 and 74, drawn to 52 (fifty-two) different polypeptides, classified in class 530, subclass 350, for example.

III. Claims 36-38, drawn to antibodies to 52 (fifty-two) different proteins, classified in class 530, subclass 387.1, fro example.

IV. Claim 39, drawn to a method of inducing an immune response by administering any one of 52 (fifty-two) different proteins, classified in class 514, subclass 2, for example.

V. Claims 40-43, drawn to a method for identifying a compound involving a polypeptide, classified in class undetermined, subclass undetermined, for example.

VI. Claim 44, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

VII. Claims 45-46, drawn to a method for identifying a compound involving nucleic acids, classified in class undetermined, subclass undetermined, for example.

IIX. Claim 47, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

IX. Claims 48-51, drawn to a method for identifying a compound involving polypeptide, classified in class undetermined, subclass undetermined, for example.

X. Claim 52, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

XI. Claims 53-55, drawn to a method of identifying an animal homolog, classified in class undetermined, subclass undetermined, for example.

XII. Claims 56-57, drawn to a method of screening a human subject, classified in class undetermined, subclass undetermined, for example.

XIII. Claims 58-61, drawn to a method of screening for an ion-x mental disorder genotype, classified in class undetermined, subclass undetermined, for example.

XIV. Claim 62, drawn to a kit for screening a human subject, classified in class 536, subclass 23.1, fro example.

XV. Claim 63, drawn to a method for identifying an ion channel allelic variant, classified in class undetèrmined, subclass undetermined, for example.

XVI. Claim 69, drawn to a method for identifying a modulator of biological activity, classified in class undetermined, subclass undetermined, for example.

XVII. Claims 70, 72-73, drawn to a method to identify compound useful for the treatment of a disorder, classified in class undetermined, subclass undetermined, for example.

XIIX. Claims 71-73, drawn to a method for identifying a compound useful as a modulator of binding, classified in class undetermined, subclass undetermined, for example.

XIX. Claims 76, 79-80, 81-83 and 87-88, drawn to nucleic acid molecules, vectors and host cells, classified in class 435, subclass 69.1, for example.

XX. Claims 77-78, 81-84 and 86-87, drawn to nucleic acids, vectors and host cells, classified in class 435, subclass 69.1, for example.

XXI. Claim 85, drawn to an antisense oligonucleotide, classified in class 536, subclass 24.5, for example.

XXII. Claims 89-94, drawn to polypeptides, classified in class 530, subclass 350, for example.

XXIII. Claim 97, drawn to a method of inducing an immune response, classified in class 514, subclass 2, for example.

XXIV. Claims 98-99, drawn to a method for identifying a compound involving a polypeptide, classified in class undetermined, subclass undetermined, for example.

XXV. Claim 100, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

XXVI. Claim 101, drawn to a method for identifying a compound involving a nucleic acid, classified in class undetermined, subclass undetermined, for example.

XXVII. Claim 102, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

XXIIX. Claims 103-104, drawn to a method for identifying a compound which modulates an ion channel, classified in class undetermined, subclass undetermined, for example.

XXIX. Claim 105, drawn to a compound, classified in class undetermined, subclass undetermined, for example.

XXX. Claim 106, drawn to a method for screening a human subject, classified in class undetermined, subclass undetermined, for example.

XXXI. Claim 107, drawn to a kit for screening a human subject, classified in class 536, subclass 23.1, for example.

XXXII. Claim 108, drawn to a method of identifying an ion channel allelic variant, classified in class undetermined, subclass undetermined, for example.

XXXIII. Claims 109-110, drawn to a polynucleotide, classified in class 536, subclass 23.1, for example.

XXXIV. Claim 111, drawn to a method for identifying a modulator of biological activity, classified in class undetermined, subclass undetermined, for example.

XXXV. Claims 112, 114-115, drawn to a method to identify compounds useful for treatment a disorder, classified in class undetermined, subclass undetermined, for example.

XXXVI. Claims 113-115, drawn to a method for identifying a compound useful as a modulator of binding, classified in class undetermined, subclass undetermined, for example.

XXXVII. Claim 116, drawn to a receptor, classified in class 530, subclass 350, for example.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I and polypeptides of Group II are

distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, antibodies of Group III can also be used in materially different methods, such as in various diagnostic (e.g. as a probe in immunoassays or immunochromatography), or therapeutic methods.

6. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II and antibodies of group III are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and entirely different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein.

7. Inventions IV, V, VII, IX, XI, XII, XIII, XV, XVI, XVII, XIIX, XXIII, XXIV, XXVI, XXIIX, XXX, XXXII, XXXIV, XXXV and XXXVI are unrelated. Inventions are unrelated if it

can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

8. Inventions I, XIX, XX and XXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the nucleic acids of inventions I, XIX, XX and XXXII have different structure, different functions and are not required one for the other.

9. Inventions XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polynucleotides of Group XX could be used in entirely different manner such as for production of polypeptides, which makes these two inventions independent and distinct.

10. Inventions II, XXII and XXXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of

inventions II, XXII and XXXVII have different structure, different functions and are not required one for the other.

11. Inventions VI, IIX, X, XIV, XXV, XXVII, XXIX and XXXI are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the compounds and kits of the Groups above are not disclosed to be used together and therefore represent patentably distinct inventions.

12. Inventions I and (VII, XI, XII, XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I could be used in an entirely different manner such as for the production of proteins rather than in the methods of Groups (VII, XI, XII, XIII).

13. Inventions I and (IV, V, VI, IIX, IX, X, XIV, XV, XVI, XVII, XIIX, XXI, XXII, XXIII-XXXVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the nucleic acids of Group I are not required for the inventions of Groups (IV, V, VI, IIX, IX, X, XIV, XV, XVI, XVII, XIIX, XXI, XXII, XXIII-XXXVI).

14. Inventions II and (V, IX, XVII, XIIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II could be used in an entirely different manner such as for the production of antibodies rather than in the inventions of Groups (V, IX, XVII, XIIX).

15. Inventions II and (IV, VI, VII, IIX, X-XVI, XIX-XXXVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Group II are not required for the inventions of Groups (IV, VI, VII, IIX, X-XVI, XIX-XXXVI).

16. Inventions III and (IV-XXXVI) are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Group III are not required for the inventions of Groups (IV-XXXVI).

17. Inventions (XIX, XX, XXI, XXI, XXXIII) and (III-XXIIX, XXIII-XXXI, XXXIII-XXXVI) are unrelated, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions are not required one for the other and are not shown to be capable of use together, therefore representing patentably different and independent inventions.

18. Inventions (VI, IIX, X, XIV, XXV, XXVII, XXIX and XXXI) and (IV, V, VII, IX, XI, XII, XIII, XV, XVI, XVII, XIIX, XXIII, XXIV, XXVI, XXIIX, XXX, XXXII, XXXIV, XXXV and XXXVI) are unrelated, too. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the compounds and kits of Groups (VI, IIX, X, XIV, XXV, XXVII, XXIX and XXXI) can be used independently and/or for different methods and inventions rather than for the methods of Groups (IV, V, VII, IX, XI, XII, XIII, XV, XVI, XVII, XIIX, XXIII, XXIV, XXVI, XXIIX, XXX, XXXII, XXXIV, XXXV and XXXVI).

19. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. In case Group I is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different types of promoter (claim 12) and different types of host cells (claim 21).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7 and 20, respectively, are generic.

21. In case Group V is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different kinds of protein binding assay.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 40 is generic.

22. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
January 29, 2002

JOHN ULM
PRIMARY EXAMINER
GROUP 1800